IRELL & MANELLA LLP
Alexander F. Wiles (CA 73596) awiles@irell.com
Brian Hennigan (CA 86955) bhennigan@irell.com
Trevor V. Stockinger (CA 226359) tstockinger@irell.com
S. Albert Wang (CA 250163) awang@irell.com
1800 Avenue of the Stars, Suite 900
Los Angeles, California 90067-4276
Telephone: (310) 277-1010
Facsimile: (310) 203-7199

ARNOLD & PORTER LLP
Kenneth A. Letzler (Admitted *Pro Hac Vice*) Kenneth_Letzler@aporter.com
Daniel S. Pariser (Admitted *Pro Hac Vice*) Daniel_Pariser@aporter.com
Barbara H. Wootton (Admitted *Pro Hac Vice*) Barbara_Wootton@aporter.com
555 Twelfth Street, NW
Washington, DC 20004-1206
Telephone: (202) 942-5000
Facsimile: (202) 942-5999

Attorneys for Plaintiff
GlaxoSmithKline

[ADDITIONAL COUNSEL ON SIGNATURE PAGE]

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

OAKLAND DIVISION

SMITHKLINE BEECHAM CORPORATION d/b/a/ GLAXOSMITHKLINE, Plaintiff, v. ABBOTT LABORATORIES, Defendant.	**Case No. C07-5702 (CW)** *Related per November 19, 2007 Order to* **Case No. C-04-1511 (CW)** **JOINT PRETRIAL CONFERENCE STATEMENT** **Date:** **N/A** **Time:** **N/A** **Courtroom:** **N/A** **Judge:** **Hon. Claudia Wilken**

(Caption continued on next page.)

SAFEWAY INC., *et al.*, Plaintiff, v. ABBOTT LABORATORIES, Defendant.	Case No. C07-5470 (CW) Related per November 19, 2007 Order to Case No. C04-1511 (CW) **JOINT PRETRIAL CONFERENCE STATEMENT** **Date:** **N/A** **Time:** **N/A** **Courtroom:** **N/A** **Judge:** **Hon. Claudia Wilken**
MEIJER, INC. & MEIJER DISTRIBUTION, INC., *et al.*, Plaintiff, v. ABBOTT LABORATORIES, Defendant.	Case No. C07-5985 (CW) (Consolidated Cases) Related per November 30, 2007 Order to Case No. C04-1511 (CW) **JOINT PRETRIAL CONFERENCE STATEMENT** **Date:** **N/A** **Time:** **N/A** **Courtroom:** **N/A** **Judge:** **Hon. Claudia Wilken**
RITE AID CORPORATION, *et al.*, Plaintiff, v. ABBOTT LABORATORIES, Defendant.	Case No. C07-6120 (CW) Related per December 5, 2007 Order to Case No. C04-1511 (CW) **JOINT PRETRIAL CONFERENCE STATEMENT** **Date:** **N/A** **Time:** **N/A** **Courtroom:** **N/A** **Judge:** **Hon. Claudia Wilken**

Plaintiffs Meijer, Inc., Meijer Distribution, Inc., Louisiana Drug Wholesale Co., Inc., Rochester Drug Cooperative, Inc. (on behalf of themselves and the certified class of direct purchasers of Norvir and/or Kaletra), Rite Aid Corporation, Rite Aid HDQTRS, Corp., JCG (pjc) USA, L.L.C., Maxi Drug, Inc. d/b/a Brooks Pharmacy, Eckerd Corporation, CVS Pharmacy, Inc., Caremark, L.L.C., Safeway, Inc., Walgreen Co., The Kroger Co., New Albertson's, Inc., American Sales Company, Inc., and HEB Grocery Company LP (referred to as the "Customer Plaintiffs"), plaintiff SmithKline Beecham d/b/a GlaxoSmithKline ("GSK"), and Defendant Abbott Laboratories ("Abbott"), pursuant to this Court's Standing Order for Pretrial Preparation, respectfully submit this Joint Pretrial Conference Statement.

I. THE ACTION

A. Substance of the Action

1. Plaintiffs' Contentions[1]

a. Background and parties

This is an action alleging violations of section 2 of the Sherman Act and various state law claims arising out of Abbott's 400% price hike on its drug Norvir in December 2003 and Abbott's actions related to the price increase.

Plaintiffs are GSK and the Customer Plaintiffs. Customer Plaintiffs Meijer, Inc., Meijer Distribution, Inc., Louisiana Drug Wholesale Co., Inc., and Rochester Drug Cooperative, Inc. represent a class that was certified by the Court on August 27, 2008 and defined as follows:

> [A]ll persons or entities in the United States that purchased Norvir and/or Kaletra directly from Abbott or any of its divisions, subsidiaries, predecessors, or affiliates during the period from December 3, 2003 through such time as the effects of Abbott's illegal conduct have ceased, and excluding federal governmental entities, Abbott, and Abbott's divisions, subsidiaries, predecessors, and affiliates.

8/27/08 Order Granting Plaintiffs' Motion for Class Certification, 07-5985, Dkt # 138, at 21.

b. Plaintiffs' claims

All plaintiffs contend that Abbott maintained monopoly power, or attempted to maintain monopoly power, in the market in which Kaletra competes, in violation of section 2 of the

[1] Defendant does not agree with the contentions in this section.

Sherman Act. Abbott did so in two ways: (1) by increasing the price of Norvir so much without changing the price of its bundled product (Kaletra)—effectively creating a substantial penalty on customers wishing to buy Kaletra's rivals boosted by Norvir—that an equally efficient competitor who did not sell both products in the bundle could not profitably match the price of the potentially competitive portion of the Kaletra bundle; and (2) by violating its antitrust duty to deal with respect to Norvir. In support of their claim that Abbott monopolized the market in which Kaletra competes, Plaintiffs will establish:[2]

i. That Plaintiffs' alleged market is a valid antitrust market;

ii. Abbott possessed monopoly power in that market when its anticompetitive conduct occurred;

iii. Abbott willfully maintained monopoly power in that market by engaging in anticompetitive conduct;

iv. Abbott's conduct occurred in or affected interstate commerce; and

v. Plaintiffs were injured in their business or property because of Abbott's anticompetitive conduct, in a manner that constitutes antitrust injury.

In support of its attempted monopolization claim, Plaintiffs will establish that:

i. Abbott engaged in anticompetitive conduct;

ii. Abbott had a specific intent to achieve monopoly power in a relevant market;

iii. There was a dangerous probability that Abbott would achieve its goal of monopoly power in the relevant market;

[2] While Customer Plaintiffs contend that they have sufficient evidence to establish all five elements listed in the text for maintenance of monopoly power, they also contend that they need establish only the following in order to prevail on their claim (because they have direct evidence of Abbott's monopoly power):

i. Abbott possessed monopoly power when its anticompetitive conduct occurred;

ii. Abbott "willfully" maintained monopoly power by engaging in anticompetitive conduct;

iii. Abbott's conduct occurred in or affected interstate commerce; and

iv. Plaintiffs were injured in their business or property because of Abbott's anticompetitive conduct.

iv. Abbott's conduct occurred in or affected interstate commerce; and

v. Plaintiffs were injured in their business or property by Abbott's anticompetitive conduct.

In support of their claim for injunctive relief, Plaintiffs Rite Aid Corporation, Rite Aid HDQTRS, Corp., JCG (pjc) USA, L.L.C., Maxi Drug, Inc. d/b/a Brooks Pharmacy, Eckerd Corporation, CVS Pharmacy, Inc., Caremark, L.L.C., Safeway, Inc., Walgreen Co., The Kroger Co., New Albertson's, Inc., American Sales Company, Inc., and HEB Grocery Company LP will establish that Abbott's unlawful conduct threatens to cause them continuing loss and damage if not enjoined by the Court.

GSK contends that Abbott's conduct constituted maintenance of monopoly power or attempted maintenance of monopoly power in violation of N.C. Gen. Stat. § 75-2.1. GSK contends that the same standards which apply to the federal Sherman Act also apply to § 75-2.1, so that GSK's evidence and argument in support of its federal claims will also establish that Abbott violated § 75-2.1.

Furthermore, GSK contends that Abbott breached the covenant of good faith and fair dealing implied by law into the agreement between Abbott and GSK that provides GSK a license to promote its protease inhibitors for use with Abbott's drug Norvir. In support of this claim, GSK will establish that:

i. The boosting license agreement between Abbott and GSK was a binding contract;

ii. Abbott breached its obligation to deal with GSK fairly and in good faith; and

iii. GSK sustained damage by reason of Abbott's breach.

To the extent that Abbott raises the limitation of liability clause contained within the contract as a defense against being liable to GSK for GSK's lost profits, GSK will establish that this clause does not prevent GSK's recovery of lost profits because:

i. The clause does not apply due to Abbott's bad faith, or intentional, willful or grossly negligent misconduct.

ii. Even if the clause applies, it does not cover lost profits because lost profits for the purposes of this contract are, as a matter of fact, direct—not consequential—damages.

In the alternative, if lost profits are ultimately found to be unrecoverable for Abbott's breach of contract, GSK will establish its damages using a restitutionary measure. These damages represent the value that GSK conferred onto Abbott for the rights which Abbott, by breaching the contract, wrongfully deprived GSK of the benefit. GSK will establish that this restitutionary measure is the amount of royalty concessions that GSK granted to Abbott on a separate license to GSK's patents that Abbott needed in order to produce another Abbott drug.

In support of GSK's claim that Abbott violated the North Carolina Unfair Trade Practices Act, N.C. Gen. Stat. §75-1.1, GSK will establish:

i. That Abbott engaged in the following the unfair acts or practices, or unfair methods of competition:

a. During the negotiation of the Norvir Boosting License, Abbott was considering how to use its control over Norvir to limit competition with Kaletra, and deliberately withheld this from GSK.

b. Abbott inequitably asserted its power over Norvir by increasing Norvir's price by 400 percent to undermine and disrupt the launch and future sales of GSK's protease inhibitor Lexiva.

c. Abbott manipulated the timing of the 400 percent Norvir price increase in order to disrupt Lexiva's launch and undermine Lexiva's future sales.

d. Abbott maintained, or attempted to maintain, a monopoly in the market in which Kaletra competes.

ii. That Abbott's unfair acts or practices, or unfair methods of competition were in commerce or affected commerce;

iii. That Abbott's unfair acts or practices, or unfair methods of competition proximately caused actual injury to GSK's business; and

iv. The amount of damage to GSK's business as a result of Abbott's unfair acts or practices, or unfair methods of competition.

2. Defendant's Contentions

Abbott contends that it did not violate § 2 of the Sherman Act, breach any obligation to Plaintiff GSK, or violate any state laws as a result of its decision to change the price of Norvir on December 3, 2003.

a. Plaintiffs' Antitrust Claims

Abbott asserts that it neither had monopoly power at the time of the Norvir repricing nor attempted to maintain monopoly power in the market in which Kaletra competes. Since before the Norvir repricing, there have been strong competitors in the market in which Kaletra competes, those competitors have faced no barriers to expansion, and Kaletra's market share was falling. These factors preclude a finding of monopoly power. And, it is undisputed that Kaletra's share of the relevant market as defined by Plaintiffs has fallen to near 30%, which contradicts any claim that Abbott ever had a dangerous probability of achieving monopoly power. Competitor PIs have thrived and new competing products have launched.

Further, Abbott has never refused to sell Norvir, nor has it offered it only at a price that purchasers could not afford. To the contrary, Norvir's sales have grown exponentially since the Norvir repricing. Abbott has also never sold Kaletra or any component of it at a price below Abbott's costs.

More particularly, Abbott contends that judgment should be entered in Abbott's favor on Plaintiffs' Sherman Act monopolization claim because Plaintiffs cannot meet their burden of showing all of the following:

i. Abbott has monopoly power in the markets in which Norvir and Kaletra compete;

ii. Abbott has engaged in conduct that had anticompetitive effects in the market in which Kaletra competes;

iii. Abbott had no legitimate business justification for its pricing conduct; and

iv. The alleged anticompetitive effects of Abbott's conduct caused Plaintiffs to suffer antitrust injury.

Judgment should be entered in Abbott's favor on Plaintiffs' Sherman Act attempted monopolization claim because Plaintiffs cannot meet their burden of showing all of the following:

i. Abbott has a specific intent to control prices or destroy competition in the market in which Kaletra competes.

ii. Abbott has engaged in conduct that had anticompetitive effects in the market in which Kaletra competes;

iii. Abbott had no legitimate business justification for its pricing conduct;

iv. Abbott has a dangerous probably of achieving market power in the market for Kaletra; and

v. The alleged anticompetitive effects of Abbott's conduct caused Plaintiffs to suffer antitrust injury.

Further, even if Plaintiffs could prove the alleged monopolization, they have failed to meet their burden of calculating damages to a degree of reasonable certainty.

b. GSK's State Law Claims

Judgment should be entered in Abbott's favor on GSK's claim for breach of contract because it cannot meet its burden of showing that the Norvir price increased violated the implied covenant of good faith and fair dealing under New York law.

Even if GSK could prove its alleged breach of contract, it could recover, at most, nominal damages because of the express limitation of liability clause limiting consequential damages, such as lost profits. GSK also is not entitled to any restitutionary damages because it cannot prove a total breach. Regardless, GSK has not proven any damages to a degree of reasonable certainty.

Judgment should be entered in Abbott's favor for GSK's claim under N.C. Gen. Stat. § 75-1.1 because that claim is based entirely on the unsupportable contract claim. Even if GSK could prove a contract breach, such a breach would not satisfy the statutory standard for "unfair" conduct.

B. Relief Prayed. A detailed statement of all the relief claimed, particularly itemizing all elements of damages claimed.

1. Plaintiffs' Requested Relief

a. Customer Plaintiffs

i. Overcharge damages, trebled.

ii. Reimbursement of attorneys' fees, costs, other expenses, and pre- and post-judgment interest as appropriate.

iii. Injunctive relief (Non-Class Customer Plaintiffs only).

(a) Permanently enjoining Abbott from continuing its unlawful conduct.

(b) Requiring Abbott to take affirmative steps to dissipate the anticompetitive effects of its prior violations.

b. GSK

i. Lost profits damages, trebled, for Abbott's violation of section 2 of the Sherman Act claim and/or Abbott's violation of N.C. Gen. Stat. §§ 75-1.1, 75-2.1.

ii. Lost profits damages for Abbott's breach of the covenant of good faith and fair dealing.

iii. Restitutionary damages, in the event that lost profits damages are unavailable, for Abbott's breach of the covenant of good faith and fair dealing.

iv. Pre- and post-judgment interest on damages as appropriate.

v. Reimbursement of attorneys' fees and costs, and other expenses.

2. Defendant's Requested Relief

a. Dismissal with prejudice of all plaintiffs' claims

b. Attorney's fees and costs as provided by law.

II. THE FACTUAL BASIS OF THE ACTION

A. Undisputed Facts. A plain and concise statement of all relevant facts not reasonably disputed.

On December 13, 2002, Abbott and GSK entered into a license permitting promotion of GSK's products for co-prescription and co-administration with Norvir. This license is a binding contract between Abbott and GSK.

Abbott Laboratories is an Illinois corporation with its principal place of business in Abbott Park, Illinois.

At the time this case was filed, in November 2007, GSK was a Pennsylvania corporation with its headquarters in Research Triangle Park (Durham), North Carolina and Philadelphia, Pennsylvania. GSK's North Carolina locations were the base for the company's research and development facilities and commercial operations in the HIV/AIDS area, and also housed various sales and marketing, administrative, and corporate functions.

The pharmaceutical products at issue in this case are sold in the State of California, the State of North Carolina, and throughout the United States.

The pharmaceutical products at issue in this case are sold in interstate commerce.

The geographic scope of the market in which Kaletra competes, for purposes of evaluating the effect on competition of the Abbott's actions at issue in this case, is the United States.

B. Disputed Factual Issues. A plain and concise statement of all disputed factual issues which remain to be decided.

1. Plaintiffs' Facts[3]

Abbott introduced Norvir (ritonavir) in March 1996, and it quickly became predominantly used in low doses as a booster of other protease inhibitors ("PIs"). From its introduction in 1996 to December 2003, Abbott never took a price increase on Norvir above 3.9 percent. In September 2000, Abbott successfully introduced its own boosted PI, Kaletra, a co-formulation of the PI

[3] Defendants disagree not only with the facts in this section, but also with the characterizations of facts herein.

lopinavir with a 200 milligram boosting dose of ritonavir. Kaletra quickly became the dominant boosted PI.

Abbott encouraged competitors to boost their PIs with Norvir, licensing effectively all of the manufacturers of boostable PIs that competed with Kaletra. One of the companies Abbott approached for a license was GSK. The Abbott-GSK negotiations eventually reached an impasse over whether GSK would pay royalties on U.S. sales, as the two sides had differing views on whether GSK needed the license in the U.S. This disagreement was resolved when the negotiations over the boosting license were coupled with negotiations over another license, in which Abbott was seeking access to GSK's technology for use in a separate Abbott drug. On December 13, 2002, Abbott and GSK executed the boosting license, providing GSK rights to promote its protease inhibitors for co-prescription with Norvir. The final boosting license required GSK to pay up-front fees, as well as royalties on sales of GSK's PIs (whether or not boosted with Norvir) outside of the U.S.; royalties on U.S. sales were due beginning in 2013. In lieu of current U.S. royalties, GSK agreed to reduce the royalty cap on the accompanying license, where Abbott was paying for GSK's technology. Abbott concluded that GSK's concession was worth more in present value terms than all of the other consideration GSK had agreed to pay to Abbott.

Also in 2002, around the same time as the negotiations with GSK, Abbott learned that two new, potentially superior PIs were poised to challenge Kaletra: GSK's Lexiva and Bristol-Myers-Squibb's Reyataz. Abbott recognized that these PIs, boosted with Norvir, presented serious threats to Kaletra's dominance. Thus, Abbott began to evaluate options for using its control over Norvir to undermine its boosted PI competitors, including withdrawing Norvir from the market as a stand-alone product (leaving Kaletra as the only source of ritonavir in the U.S.) and raising Norvir's price. Although it was clear that the purpose of the GSK-Abbott license agreement was to allow GSK to increase the sales of Lexiva by promoting it for use with Norvir, Abbott elected not to inform GSK of Abbott's evaluation of these options for using Norvir to cripple boosted PIs that were going to compete with Kaletra.

Abbott's evaluation of options for using its control over Norvir to impede competition with Kaletra continued into 2003, when Abbott considered—in addition to a dramatic price increase

and withdrawing Norvir entirely from the market—pulling the soft-gel capsule formation of Norvir so that it would be available only in its foul-tasting liquid form. Abbott's concern about the competitive challenges presented by Reyataz and Lexiva increased when studies showed that Reyataz and Lexiva, were, when boosted, as effective as Kaletra and also more convenient. In July 2003, Reyataz was introduced to the U.S. market, causing Kaletra's market share to fall further and more rapidly than Abbott anticipated. Abbott also was aware that GSK was about to introduce Lexiva into the market in November of 2003, creating a further sense of urgency for Abbott. The Abbott worries about new competitors increased even more as Abbott realized its strategies to present Kaletra as superior to Reyataz and Lexiva appeared to be failing.

By September 2003, Abbott has narrowed its strategy to address the Reyataz and Lexiva threats to two options: withdraw the Norvir soft gel capsules from the market or implement a mega-price increase on Norvir.

In October 2003, Abbott's CEO approved a 400 percent price hike on Norvir. Abbott waited to implement the price increase until early December 2003, just after GSK's Lexiva launch in November 2003, to stymie Lexiva before it could get established. The 400% price increase caused the price of a daily dose of boosted Lexiva, which included 200 mg of Norvir, to go from a $0.67 per day premium over Kaletra to a $14.39 per day premium—overnight. Boosted Reyataz went from a $5.03 per day premium to a $11.89 per premium.

The price hike was so large relative to the price at which Abbott was selling ritonavir in Kaletra that it caused the imputed price of the lopinavir portion of Kaletra to fall below Abbott's average variable costs of producing and selling lopinavir. As a result, a hypothetical, equally efficient rival could not earn a profit pricing competitively with Kaletra (even assuming that any such competitor was not already adequately discouraged by Abbott's ability to raise Norvir price even further). This disadvantage was further aggravated by the way government pricing rules would force any competitor's responsive price cut to be so overly-broad that it would ultimately be self-defeating.

The magnitude of Abbott's price hike was unprecedented. No one had anticipated a price increase of this size. Even Abbott had to scramble to get out of its contracts to avoid becoming obligated for certain payments as a result of the hike.

The HIV community expressed outrage at the hike. Physicians went into "lock-down" mode, so that GSK could not, during the crucial launch period, market Lexiva and educate doctors about GSK's new drug. The controversy was further stoked by Abbott's misleading communications to the public regarding the true reasons for the price hike and Abbott's alleged remedial steps. The FDA even warned Abbott to cease using a cost comparison chart, which the FDA deemed to be misleading.

The 400% price increase had its intended anticompetitive effect: it caused Reyataz's market share rise to slow dramatically; it significantly disrupted GSK's Lexiva launch in November 2003; and it caused Kaletra to maintain its dominant position for several years longer than it would have, but for Abbott's unlawful conduct, by substantially slowing its market share decline. Moreover, by impairing its rivals in the market in which Kaletra competes, Abbott was able to increase Kaletra's price by 25% from 2005 to 2007.

Abbott's conduct permanently harmed Lexiva's market performance; GSK lost hundreds of millions of dollars of profits when Lexiva sales fell far short of GSK, Abbott and independent third party expectations. Meanwhile, Abbott succeeded in overcharging the Customer Plaintiffs by more than $1 billion on the combined sales of Norvir and Kaletra.

Several of the individual Customer Plaintiffs bring their antitrust claims pursuant to valid assignments they received from the wholesalers from which they purchase Norvir and Kaletra. The assignor-wholesalers are direct purchasers of Norvir and Kaletra and have assigned to these individual Customer Plaintiffs any antitrust claims the wholesalers may have relating to Norvir and Kaletra resold to them.

2. Defendant's Facts[4]

This case focuses on the relationship between the prices for two prescription drugs products that are supplied by Abbott Laboratories to treat the HIV virus and AIDS. These two drugs are called Norvir® and Kaletra®. There are many different kinds of HIV drugs. HIV patients take multiple drugs at one time, referred to as a cocktail, to treat their disease.

The U.S. Food and Drug Administration, or FDA, originally approved the Norvir soft gel capsule in March 1996 to treat HIV infection. Norvir's active ingredient is ritonavir. When the Norvir soft gel capsule was originally approved, ritonavir was approved as a protease inhibitor, or a PI. As a PI, Norvir's daily dose was 1,200 milligrams of ritonavir. That is 12 pills per day. At this dosage level, Abbott charged about $18 per day, which was typical at the time for HIV drugs.

In its continuing research and testing, Abbott also discovered that a very low dose of ritonavir would boost the effectiveness of other PIs in HIV patients. This meant that low ritonavir doses could be used to keep other PIs in patients' bloodstreams for longer periods of time, which would make those other PIs more effective. For instance, when combined with small amounts of ritonavir, other PIs can be used at lower doses with lower toxicities. When it is used in these low boosting doses, ritonavir is not itself working as a PI at all. Instead, it essentially works as a stopper in the body's plumbing that would otherwise quickly eliminate the other PI from the bloodstream. The United States Patent Office granted Abbott patents for various aspects of ritonavir's use as a booster for other PIs.

In 2000, Abbott introduced the Kaletra soft gel capsule, a pill that combined an Abbott PI called lopinavir with ritonavir, in a liquid solution encapsulated in a soft gel coating.

As its clinical value increased due to its boosting properties, Norvir's daily price decreased due to its declining dose. From 12 pills per day in 1996, the average dose gradually declined as more and more patients used Norvir in low doses as a booster. That decline accelerated in July 2003 when the FDA gave another drug company, Bristol Meyers-Squibb, permission to promote a 100 mg dose of Norvir to boost its own PI, Reyataz. That is only one Norvir pill.

[4] Plaintiffs disagree not only with the statement of the facts in this section, but with its characterization of Plaintiffs' claims and theories as well.

Within months of Reyataz's launch, Norvir's most common dose dropped to 100 mg per day of ritonavir, at a cost of $1.71. Thus, although ritonavir's clinical value had increased substantially, its daily price for this most common dose had decreased from about $18 to just $1.71. HIV drugs typically cost $20 to $50 per day.

In December 2003, Abbott increased the wholesale price of a Norvir capsule containing 100 mg of ritonavir from $1.71 to $8.57. Abbott legitimately re-priced Norvir with the purpose and effect of aligning its price with ritonavir's new and patented use as a low-dose PI booster. Abbott did not raise the price of Kaletra when it raised Norvir's price. Abbott introduced a tablet form of Kaletra in October 2005 and a tablet form of Norvir in early 2010. Abbott's pricing of Kaletra during the relevant period has not exceeded competitive levels or been below cost.

In November 2003, Abbott's competitor, GSK—a plaintiff in this case—released its own PI. This PI is called Lexiva. Abbott and GSK entered into a license that allowed GSK to market Lexiva as a PI that could be boosted by Norvir despite Abbott's patent rights covering that method of treatment.

The remaining plaintiffs are wholesalers who purchased Norvir and Kaletra from Abbott, or pharmacies that purchased Norvir and Kaletra from the wholesalers, during the relevant period, which is from December 2003 through the present. The extent of the pharmacies' assignments of claims from the wholesalers is unclear and in dispute.

All Plaintiffs allege that Abbott violated Section 2 of the federal antitrust law called the Sherman Act when it increased the wholesale daily price of the Norvir capsule containing 100 mg of ritonavir from $1.71 to $8.57 in December 2003 without also increasing the price of Kaletra. According to Plaintiffs, the resulting smaller price difference between Norvir and Kaletra prevented rival boosted PI regimens from competing with Kaletra, thus allegedly allowing Abbott unlawfully to maintain a monopoly for the market in which they allege Kaletra competes.

Plaintiff GSK further alleges that the timing and extent of the Norvir repricing, which coincided with GSK's launch of Lexiva, breached GSK's license agreement with Abbott and violated North Carolina's unfair trade practices statutes.

Abbott denies all of plaintiffs' claims. Abbott legitimately re-priced Norvir to align its price with ritonavir's new and patented use as a low-dose PI booster, not unlawfully to monopolize the market in which Kaletra competes. Abbott states, among other things, that its conduct did not violate any applicable legal standard, was not anticompetitive, did not cause any anticompetitive effects, did not cause Abbott to obtain or maintain a monopoly, did not create a dangerous probability that Abbott would obtain or maintain a monopoly, and did not breach its license agreement with GSK. Abbott further disputes that plaintiffs are entitled to recover any damages as a result of its conduct.

C. Agreed Statement. A statement assessing whether all or part of the action may be presented upon an agreed statement of facts.

The parties do not see believe any part of the case that may be presented for decision based upon an agreed statement of facts.

D. Stipulations. A statement of stipulations requested or proposed for pretrial or trial purposes.

1. The parties reached a stipulation, that was signed by the Court, regarding disclosure of demonstrative exhibits no less than 72 hours ahead of their use. *See, e.g.*, 07-5702, Dkt # 322.

2. The parties reached a stipulation, that was signed by the Court, regarding the filing of objections to trial exhibits and a means of focusing the parties' meet-and-confer related thereto. *See, e.g.*, 07-5702, Dkt. # 328.

3. The parties have filed a stipulation, currently pending Court approval, seeking an extension of the deadline for filing jury instructions and verdict forms, so that the parties may continue their meet-and-confer efforts. *See, e.g.*, 07-5702, Dkt. #327.

4. The parties entered into a stipulation related to the Fed. R. Civ. P. 30(b)(6) testimony of certain direct purchaser corporate representatives. *See, e.g.*, 07-cv-05470, Dkt. # 104.

5. The parties have agreed that they will not object to the use of documents at trial on the basis that the documents were not listed on the party's exhibit list, if an exact duplicate of the document is listed on the party's exhibit list.

6. The parties agree that no party will inform the jury of the fact that the damages relating to Plaintiffs' federal antitrust claims and to GSK's North Carolina statutory claims are trebled. Furthermore, all the parties agree that no party will inform the jury that attorneys will be compensated pursuant to a fee shifting statute like the Clayton Act § 15.

7. The parties agree that all percipient witnesses will be excluded from the courtroom except for one representative per party. Furthermore, no percipient witnesses may read daily transcripts of court proceedings, but expert witnesses shall not be covered by this prohibition. All parties also agree that each party may designate no more than one party representative at trial.

8. The parties agree that no party will make any reference before the jury to the settlement in *Doe v. Abbott Labs.*, Case No. 04-cv-1511-CW (N.D. Cal.).

9. In an effort to streamline trial, the parties will continue to confer on issues related to notice and presentment of live testimony at trial.

III. DISPUTED LEGAL ISSUES. Without extended legal argument, a concise statement of each disputed point of law concerning liability or relief.

A. <u>Plaintiff's Statement of Disputed Legal Issues</u>

1. Did Abbott's 400% Norvir price hike and surrounding actions constitute a violation of the antitrust laws under the theory set out in *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585 (1985)?

2. Did Abbott's 400% Norvir price hike and surrounding actions constitute a violation of the antitrust laws under the theory set out in *Cascade Health Solutions v. PeaceHealth*, 515 F.3d 883 (9th Cir. 2008)?

3. If proven, does Abbott's contention that Kaletra's market share declined negate, by itself, a finding of monopoly power as a matter of law?

4. Can plaintiffs state a claim for attempted monopolization when they contend that Abbott had a monopoly and engaged in anti-competitive conduct in an attempt to maintain that monopoly longer than would otherwise have occurred?

5. If the Customer Plaintiffs are able to prove that they were overcharged as a result of a violation by Abbott of the antitrust laws, are their overpayments on purchases of Norvir, Kaletra, or both, compensable antitrust injuries?

6. Did Abbott breach the implied covenant of good faith and fair dealing contained within the license agreement into which GSK and Abbott entered on December 13, 2002 ("Norvir Boosting License")?

7. Are lost profits damages available to GSK as a remedy for Abbott's alleged breach of the implied covenant of good faith and fair dealing?

8. Are GSK's lost profits damages covered by the limitation of liability clause found in the Norvir Boosting License, and if so, is that clause enforceable?

9. Is GSK entitled to restitutionary damages for Abbott's alleged contract breach measured, as GSK contends, by GSK's claimed concession to Abbott on the simultaneously executed license in which Abbott licensed GSK's technology?

10. Did Abbott's 400% Norvir price hike and surrounding actions constitute an anticompetitive or unfair trade practice under N.C. Stat. § 75-1.1?

11. Did Abbott's 400% Norvir price hike and surrounding actions constitute a violation of the antitrust laws under the theory set out in *Conwood Co. v. U.S. Tobacco Co.*, 290 F.3d 768 (6th Cir. 2002)?[5]

12. Did Abbott's 400% Norvir price hike and surrounding actions constitute a violation of the antitrust laws by leveraging a monopoly from one market into another in order to evade price regulation, thus harming consumers?

B. Defendant's Statement of Disputed Issues[6]

1. Antitrust Claims

1. The legal standards applicable to a claim for predatory pricing of Kaletra, including but not limited to whether:

[5] Plaintiffs list this Issue and Issue # 12 to preserve them for appeal.

[6] Abbott reserves its rights to challenge on appeal any pretrial ruling of this Court.

a. The Cascade discount attribution test is used and whether the plaintiffs must show recoupment;

b. How to apply the discount attribution test to Kaletra;

c. The existence of a legitimate business justification can defeat a claim of predatory pricing in the form of bundled discounting;

d. How to determine whether a product constitutes a bundle of two separate products; and

e. Whether these standards are satisfied here.

2. Whether and, if so, when direct purchasers can suffer antitrust injury from predatory pricing, and what damages are potentially available to direct purchasers for predatory pricing, including whether the direct purchasers' alleged overcharges on Norvir can properly be found to constitute antitrust injury.

3. The legal standard applicable to showing a Sherman Act Section 2 violation based upon an alleged refusal to deal, including whether such a claim can be stated based upon a differential between the prices of two of a defendant's products where neither product is priced below cost and there has been no substantial foreclosure in the sales of either product as a result of the price differential.

4. Whether direct purchasers have standing to bring refusal-to-deal claims.

5. The standards applicable to finding monopoly power, including whether monopoly power can be found where the market share of the defendant's product is decreasing and the defendant's product is no longer the market leader.

6. Whether an attempted monopolization claim may be stated where the defendant's market share has been decreasing and the defendant's product is no longer the market leader.

7. The appropriate method for calculating market share in the market in which Kaletra competes.

8. The standards for determining the relevant product market, including whether the plaintiff must show the extent of cross-elasticity of demand among products potentially within the relevant product market.

9. Whether an alleged decrease in innovation may count as an anticompetitive effect under the Sherman Act, and, if so, what standard of proof applies to the allegation that alternative products would have existed but for the defendant's alleged conduct.

10. Whether and, if so, the circumstances under which a Sherman Act Section 2 claim can be stated based upon a defendant's unilaterally increasing the price of a patented product.

2. Breach of the Covenant of Good Faith and Fair Dealing

1. Whether GSK may assert an implied covenant of good faith and fair dealing claim in absence of a viable breach of contract claim;

2. Whether GSK may prove a breach of the implied covenant absent a contractual provision giving Abbott discretion over a particular element of performance under the license agreement;

3. Whether the integration and warranty provisions in the license agreement bar GSK from establishing a breach of the implied covenant;

4. Whether the implied covenant precludes a patentee that agrees to license its patented invention to a competitor from competing with the licensee in sales of products using the patented invention;

5. Whether the implied covenant can be construed to create independent contractual rights;

6. Whether GSK must prove that the obligation Abbott allegedly breached is in aid and furtherance of the express terms of the parties' license agreement;

7. Whether the implied covenant permits the Court to imply a promise on an issue the parties specifically avoided negotiating;

8. Whether the implied covenant can come into play when the contract is intentionally silent on the term GSK seeks to imply;

9. Whether GSK must prove that no reasonable party in its position would have entered into the contract without an understanding that Abbott promised to make Norvir commercially available and keep future increases in the price of Norvir in line with past increases;

10. Whether GSK's interpretation of the parties' agreement would render that agreement an illegal price-fixing agreement;

11. Whether GSK may prove a breach of the implied covenant of good faith and fair dealing where the promise allegedly breached would (or at least arguably would) constitute an antitrust violation had the parties expressly agreed to it;

12. Whether a party is entitled to recover lost profits for a breach of the implied covenant of good faith and fair dealing;

13. Whether the limitation of liability provision in the license agreement precludes GSK from obtaining lost profits damages;

14. Whether, to avoid application of the limitation of liability provision, GSK must prove that Abbott's conduct involves a breach of a fundamental, affirmative obligation that the license agreement expressly imposes on Abbott;

15. Whether, to avoid application of the limitation of liability provision, GSK must prove that Abbott engaged in tortious misconduct – that is, willful, wanton and grossly negligent acts;

16. Whether the "bad faith" breach exception to the New York rule enforcing exculpatory clauses applies only to breaches of express contractual provisions; and

17. Whether GSK is entitled to restitutionary damages.

3. North Carolina Unfair and Deceptive Trade Practices Act

a. Alleged Anticompetitive Conduct

1. Whether a finding that Abbott's conduct does not violate the Sherman Act would preclude GSK from establishing that such conduct violates the UDTPA.

2. Whether the North Carolina Supreme Court would adopt the Ninth Circuit's bundled discounting and refusal to deal precedents in interpreting the scope of the UDTPA.

3. Whether a finding that Abbott's conduct violates the Sherman Act under Ninth Circuit law would be sufficient to establish that such conduct violates the UDTPA.

b. Alleged Contractual Misconduct

4. Whether Abbott's conduct constitutes a "substantial aggravating circumstance" such that its alleged breach constitutes an unfair practice under the UDTPA.

5. Whether GSK must prove that Abbott had no intent to perform its obligations under the license agreement to establish that Abbott's conduct in connection with the license agreement is an unfair practice in violation of the UDTPA.

6. Whether GSK must show that it suffered actual injury as a proximate result of conduct by Abbott that is found to be an unfair practice.

IV. FURTHER DISCOVERY OR MOTIONS. A STATEMENT OF ALL REMAINING DISCOVERY OR MOTIONS.

A. Remaining Discovery

1. Customer Plaintiffs[7] served a deposition notice for Miles White, Abbott's CEO, on January 18, 2011. Defendant objected to the notice. The meet-and-confer process over this began thereafter, and plaintiffs have stated that they may bring a motion before Magistrate Judge Zimmerman.

2. The Customer Plaintiff Opt-Outs produced additional documents today that they say they intend to use at trial. They also stated an intent to produce a supplemental expert report. Abbott contends that these untimely materials should be excluded.

B. Remaining Motions

1. Plaintiffs and Defendant have filed motions *in limine*.

2. The parties have not reached agreement on all jury instructions, and will submit promptly argument on the contested jury instructions for the Court's decision.

[7] Plaintiff GSK does not join in the effort to depose Miles White.

3. The Customer Plaintiffs filed a motion for bifurcation (*see* Part V.C below) and an administrative motion for briefing and hearing on the underlying motion on shortened time.

4. A further motion may be necessary regarding the Customer Plaintiff Opt-Outs' production of additional materials, and stated intent to produce a supplemental expert report.

V. TRIAL ALTERNATIVES AND OPTIONS.

A. Settlement Discussion. A statement summarizing the status of settlement negotiations and indicating whether further negotiations are likely to be productive.

The parties participated in mediation in November 2010. No settlement was reached and no further negotiations have taken place.

B. Consent to Trial Before a Magistrate Judge. A statement whether the parties consent to a court or jury trial before a magistrate judge, with appeal directly to the Ninth Circuit.

The parties do not consent to a court or jury trial before a magistrate judge.

C. Bifurcation, Separate Trial of Issues. A statement of whether bifurcation or a separate trial of specific issues is feasible and desired.

On January 21, 2011, Customer Plaintiffs filed a motion, *e.g.*, 07-5470, Dkt. # 265, seeking bifurcation. Plaintiffs propose that liability, causation, and fact of damage would be tried first, followed by a damages phase with the same jury for GSK's claims only, and then a separate damages phase with a different jury for determining the amount of the Customer Plaintiffs' damages. This Bifurcation Motion was accompanied by a Motion to Shorten Time for briefing and hearing, with a requested argument on bifurcation at the pretrial conference on February 8, 2011. *E.g.*, 07-5470, Dkt. # 269. Abbott has filed an opposition to the Motion to Shorten Time. *E.g.*, 07-5470, Dkt. # 271. Abbott will also substantively oppose the motion to bifurcate. The Bifurcation Motion is not yet submitted. The Motion to Shorten Time was submitted as of January 24, 2011.

VI. MISCELLANEOUS. Any other subjects relevant to the trial of the action, or material to its just, speedy and inexpensive determination.

A. Deposition Designations, Counter-Designations, and Objections

In a stipulation that the Court has signed, the parties agreed to exchange counter-designations for depositions and objections to the original deposition designations on February 4, 2011. *See, e.g.*, 07-5702, Dkt. # 328. Based on the Court's guidance, rendered in approving this stipulation, the parties will not be filing any deposition designations, objections to original deposition designations, deposition counter-designations, or objections to counter-designations, until 14 days before a particular deposition is to be read. At that time, the parties will file a single, color-coded transcript indicating designations and counter-designations, along with objections noted in the margins.

B. Trial Date

The parties will be ready for trial on February 22, 2011.

C. Further Meet-and-Confer Discussions

The parties intend to meet and confer further before the pre-trial conference in order to further limit the issues that the Court will have to address.

Dated: January 25, 2011

Respectfully submitted,

IRELL & MANELLA LLP

By: */s/ Alexander F. Wiles*
Alexander F. Wiles

LIEFF, CABRASER, HEIMANN & BERNSTEIN, LLP

By: */s/ Brendan P. Glackin*

Joseph R. Saveri
Brendan P. Glackin
Sarah R. London
275 Battery Street, 29th Floor
San Francisco, CA 94111-3339
Telephone: (415) 956-1000
Facsimile: (415) 956-1008
Email: jsaveri@lchb.com, bglackin@lchb.com, slondon@lchb.com

Local Counsel for the Direct Purchaser Class

DILLINGHAM & MURPHY, LLP
William Francis Murphy
Barbara Lynne Harris Chiang
Edward Eldon Hartley
225 Bush Street, Sixth Floor
San Francisco, CA 94104-4207
Telephone: (415) 397-2700
Facsimile: (415) 397-3300
Email: wfm@dillinghammurphy.com, bhc@dillinghammurphy.com, eeh@dillinghammurphy.com

Local Counsel for Safeway Inc., et al., and Rite Aid Corp., et al.

BERGER & MONTAGUE, P.C.
Eric L. Cramer, Pro Hac Vice
Daniel Simons, Pro Hac Vice
1622 Locust Street
Philadelphia, PA 19103
Telephone: (215) 875-3000
Facsimile: (215) 875-4604
Email: ecramer@bm.net, dsimons@bm.net

Co-Lead Counsel for the Direct Purchaser Class

GRANT & EISENHOFER, P.A.
Linda Nussbaum, Pro Hac Vice
John D. Radice, Pro Hac Vice
485 Lexington Avenue
New York, NY 10017
Phone: (646) 722-8500
Facsimile: (646) 722-8501
Email: lnussbaum@gelaw.com, jradice@gelaw.com

Co-Lead Counsel for the Direct Purchaser Class

GARWIN GERSTEIN & FISHER, LLP
Bruce E. Gerstein, Pro Hac Vice
Joseph Opper, Pro Hac Vice
1501 Broadway, Suite 1416
New York, New York 10036
Telephone: (212) 398-0055
Facsimile: (212) 764-6620
Email: bgerstein@garwingerstein.com,
jopper@garwingerstein.com

Co-Lead Counsel for the Direct Purchaser Class

KENNY NACHWALTER, PA
Lauren C. Ravkind, Pro Hac Vice
Scott Eliot Perwin, Pro Hac Vice
201 S. Biscayne Blvd.
1100 Miami Center
Miami, Florida 33131
Telephone: 305-373-1000
Facsimile: 305-372-1861
Email: sperwin@kennynachwalter.com

Lead Counsel for Safeway Inc., et al.

HANGLEY ARONCHICK SEGAL & PUDLIN
Steve D. Shadowen, Pro Hac Vice
Monica L. Rebuck, Pro Hac Vice
30 North Third Street, Suite 700
Harrisburg, PA 17101-1701
Telephone: (717) 364-1007
Facsimile: (717) 362-1020
Email: sshadowen@hangley.com,
mrebuck@hangley.com

Lead Counsel for Rite Aid Corp., et al.

ODOM & DES ROCHES, LLP
John Gregory Odom, Pro Hac Vice
Stuart E. Des Roches, Pro Hac Vice
John Alden Meade, Pro Hac Vice
Suite 2020, Poydras Center
650 Poydras Street
New Orleans, LA 70130
Telephone: (504) 522-0077
Facsimile: (504) 522-0078
Email: greg@odrlaw.com; stuart@odrlaw.com;
jmeade@odrlaw.com

SMITH FOOTE, LLP
David P. Smith, Pro Hac Vice
W. Ross Foote, Pro Hac Vice
720 Murray Street
P.O. Box 1632
Alexandria, LA 71309
Telephone: (318) 445-4480
Facsimile: (318) 487-1741
Email: dpsmith@psfllp.com; rfoote@psfllp.com

SPIEGEL LIAO & KAGAY, LLP
Charles M. Kagay (State Bar No. 73377)
Wayne M. Liao (State Bar No. 66591)
388 Market Street, Suite 900
San Francisco, California 94111
Telephone: (415) 956-5959
Facsimile: (415) 962-1431
Email: cmk@slksf.com; wml@slksf.com

KOZYAK TROPIN & THROCKMORTON
Tucker Ronzetti, Pro Hac Vice
Adam Moskowitz, Pro Hac Vice
2800 Wachovia Financial Center
200 South Biscayne Boulevard
Miami, Florida 33131-2335
Telephone: (305) 372-1800
Telecopier: (305) 372-3508
Email: tr@kttlaw.com; amm@kttlaw.com

AUBERTINE DRAPER ROSE, LLP
Andrew E. Aubertine, Pro Hac Vice
8203 SE 7th Avenue
Portland, Oregon 97202
Telephone: (503) 221-4570
Facsimile: (503) 222-3032
Email: aa@adr-portland.com

LAW OFFICES OF JOSHUA P. DAVIS
Joshua P. Davis (State Bar No. 193254)
437A Valley Street
San Francisco, CA 94131
Telephone: (415) 422-6223
Email: davisj@usfca.edu

VANEK, VICKERS & MASINI, P.C.
Joseph M. Vanek, Pro Hac Vice
David P. Germaine, Pro Hac Vice
111 South Wacker Drive, Suite 4050
Chicago, IL 60606
Telephone: (312) 224-1500
Facsimile: (312) 224-1510
Email: jvanek@vaneklaw.com;
dgermaine@vaneklaw.com

SPERLING & SLATER
Paul E. Slater, Pro Hac Vice
55 West Monroe Street, Suite 3200
Chicago, Illinois 60603
Telephone: (312) 641-3200
Facsimile: (312) 641-6492
Email: pes@sperling-law.com

Additional Direct Purchaser Class Counsel

Dated: January 25, 2011

WINSTON & STRAWN LLP

/s/ James F. Hurst

James F. Hurst (*Admitted Pro Hac Vice*)
Charles B. Klein (*Admitted Pro Hac Vice*)
Samuel S. Park (*Admitted Pro Hac Vice*)
Nicole M. Norris (SBN 222785)
Stephanie McCallum (*Admitted Pro Hac Vice*)
101 California Street, Suite 3900
San Francisco, CA 94111-5894
Telephone: 415-591-1000
Facsimile: 415-591-1400
Email: jhurst@winston.com; cklein@winston.com;
nnorris@winston.com; smccallum@winston.com

MUNGER, TOLLES & OLSON LLP
Jeffrey I. Weinberger (SBN 56214)
Stuart N. Senator (SBN 148009)
Michelle Friedland (SBN 234124)
560 Mission Street, 27th Floor
San Francisco, CA 94105-2907
Telephone: (415) 512-4000
Facsimile: (415) 512-4077
Email: jeffrey.weinberger@mto.com;
stuart.senator@mto.com; michelle.friedland@mto.com

Counsel for Defendant Abbott Laboratories

Pursuant to General Order No. 45, Section X, I attest under penalty of perjury that concurrence in the filing of this document has been obtained from Alexander F. Wiles, Brendan P. Glackin, and James F. Hurst.

Dated: January 25, 2011

By: */s/ Trevor V. Stockinger*

Trevor V. Stockinger
IRELL & MANELLA LLP
Attorneys for GlaxoSmithKline